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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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July 29, 2002

Marilyn A. Friedly
Director, Regulatory Affairs
PharmaForce, Inc.
1507 Chambers Road
Columbus, Ohio 43212

Re: Docket No. 01P-0533/CP1

Dear Ms. Friedly:

This letter responds to your citizen petition dated November 28, 2001, requesting the Food and Drug Administration (FDA) to determine whether cyanocobalamin injection (Rubramin) was voluntarily withdrawn or withheld for sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that cyanocobalamin injection (Rubramin), NDA No. 06-799, was not withdrawn from sale for reasons of safety or effectiveness. The FDA will maintain cyanocobalamin injection (Rubramin) in the "Discontinued Drug Product List" section of the Orange Book.

Enclosed is a copy of the Federal Register notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-5648.

Sincerely,

J. Kenneth Borgerding
Office of Regulatory Policy
Center for Drug Evaluation and Research

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Enclosure

CONTESTING RECORD PROCEDURES:

Write to either of the System Managers listed above, at the address noted, identifying the record and specifying the information to be contested and corrective action sought, together with supporting justification to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

All items of information contained in the system of records are obtained from the States.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–18885 Filed 7–25–02; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0563]

Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc.; Revocation of U.S. License Nos. 1030, 1031, 1032, and 1033

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033) issued to Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc., for the manufacture of Source Plasma. These establishments did not respond to a notice of opportunity for a hearing on a proposal to revoke their licenses.

DATES: The revocation of the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033) is effective July 26, 2002.

FOR FURTHER INFORMATION CONTACT: Earline Robinson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is revoking the biologics license (U.S. License No. 1030) issued to Beauregard Plasma, Inc., P.O. Box 96, Hwy. 27, DeQuincy, LA 70633; the biologics license (U.S. License No. 1031) issued to Jackson Plasma, Inc., P.O. Box 788, Hwy. 68, Jackson, LA 70748; the biologics license (U.S. License No. 1032) issued to Baton Rouge Plasma, Inc., P.O. Box 174, Hwy. 74, St. Gabriel, LA 70776; and the biologics license (U.S. License No. 1033) issued to Claiborne Plasma, Inc., Route 2, Box 75, Homer, LA 71040, for the manufacture of Source Plasma. FDA initiated proceedings to revoke the licenses because authorized FDA employees were unable to gain access to any of the establishments to carry out required inspections of the facilities, and manufacturing of products had been discontinued to an extent that meaningful inspections could not be made.

In a certified, return-receipt letter dated May 11, 2001, FDA notified the authorized official of the establishments that attempts to conduct inspections of the establishments were unsuccessful because the establishments were apparently no longer in operation and had apparently discontinued the manufacture of Source Plasma. The letter advised the authorized official that, under 21 CFR 601.5(b)(1)(i) and (b)(1)(ii) (formerly codified as 21 CFR 601.5(b)(1) and (b)(2)), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection under 21 CFR 600.21 or that manufacturing of a product has been discontinued to an extent that a meaningful inspection could not be made, the Commissioner of Food and Drugs shall institute proceedings for license revocation. In the same letter, FDA notified the establishments of FDA's intent to revoke U.S. License Nos. 1030, 1031, 1032, and 1033 and its intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of January 9, 2002 (67 FR 1223), a notice of opportunity for a hearing on a proposal to revoke the license of Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc. In the notice, FDA explained that the proposed license revocations were based on the inability of authorized FDA employees to conduct a meaningful inspection of the facilities because they were no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The notice provided the establishments 30 days to submit a written or electronic request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons 60 days to submit written or electronic comments on the proposed revocation. The notice also stated that a licensee's failure to file timely written requests for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation. The establishments did not respond within the 30-day time period with a written or electronic request for a hearing, and under 21 CFR 12.21(b), the 30-day time period prescribed in the notice of opportunity for a hearing may not be extended. No other comments were received.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033), issued to Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc., respectively, are revoked, effective July 26, 2002.

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19017 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0533]

Determination That Cyanocobalamin Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that cyanocobalamin injection (Rubramin PC), 1 milligram (mg)/milliliter (mL) in a 10 mL vial (cyanocobalamin injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyanocobalamin injection.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price

Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Cyanocobalamin injection (Rubramin PC), 1mg/mL in a 10 mL vial is the subject of NDA 6–799. On November 28, 1951, Bristol-Myers Squibb Co. received approval to market cyanocobalamin injection. Cyanocobalamin is vitamin B_{12}. Subsequently, Bristol-Meyers Squibb Co. withdrew cyanocobalamin injection from sale.

On November 29, 2001, PharmaForce, Inc., submitted a citizen petition (Docket No. 01P–0533) under 21 CFR 10.30 to FDA requesting that the agency determine whether cyanocobalamin injection was withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed its records and determined that cyanocobalamin injection was not withdrawn from the market for safety or efficacy reasons. Accordingly, the agency will list cyanocobalamin injection in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to cyanocobalamin injection may be approved by the agency.

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18976 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0023]

Determination of Regulatory Review Period for Purposes of Patent Extension; Definity

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Definity and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Definity (perflutren lipid microspheres). Definity is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Definity (U.S. Patent No. 5,527,521) from Dupont Contrast Imaging, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Definity represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Definity is 2,160 days. Of this time, 1,193 days occurred during the testing phase of the regulatory review period, while 967 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* September 3, 1995. The applicant claims September 13, 1995, as the date the investigational new drug application (IND) became